## 510(k) Summary

## 1.0 SUBMITTER INFORMATION

1.1 Submitter: SHIMADZU MEDICAL SYSTEMS

20101 South Vermont Ave. Torrance, CA 90502-1328

PH: 310-217-8855 FX: 310-217-8869

1.2 Contact: Randal Walker

1.3 Date: January 18, 2005

#### 2.0 DEVICE NAME

2.1 Proprietary Name: SDU-1100

2.2 Common Name: Ultrasound Imaging System

2.3 Classification: Ultrasonic Pulsed Doppler Imaging System

FR # 892.1550, Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System
FR # 892.1560, Product Code 90-IYO
Diagnostic Ultrasound Transducer
FR # 892.1570, Product Code 90-ITX

FK # 092.1370, Floquet Code 30-112

2.4 Predicate Device: GE Logiq 500 (K991611, 6/9/99)

### 3.0 DEVICE DESCRIPTION

The SDU-1100 is a mobile diagnostic ultrasound system. This system has flat linear array, convex linear and sector probe with a frequency range of approximately 2 to 15 MHz. It has B mode, M mode, Pulsed Doppler mode, Color mode, or in a combination of modes.

### 4.0 INTENDED USE

The SDU-1100 is intended for the following applications:

Fetal, Abdominal, Pediatric, Small Organs (Specify), Neonatal Cephalic, Adult Cephalic, Cardiac, Transrectal, Transvaginal, Peripheral Vascular, Musculo-skeletal Superficial and Musculo-skeletal Conventional.

### **5.0 SAFETY CONSIDERATIONS**

SDU-1100 has been designed to meet the following voluntary and measurement standards:

- IEC 60601-1 Safety of Medical Electric Equipment
- AIUM NEMA UD2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment Revision 1 (AIUM 1998)
- AIUM NEMA UD3 Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment



APR - 1 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Mr. Randal Walker National Service Manager Shimadzu Medical Systems 20101 South Vermont Avenue TORRANCE CA 90502

Re: K050510

Trade Name: SDU-1100 (Echo View/Shimasonic) Diagnostic Ultrasound Device

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: January 18, 2005 Received: March 1, 2005

#### Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SDU-1100 (Echo View/Shimasonic) Diagnostic Ultrasound Device, as described in your premarket notification:

# Transducer Model Number

<u>L040-075U</u>	
<u>L040-120U</u>	
<u>L070-075U</u>	

VA20R-035U VA40R-035U VA40R-035HU VA57R-0375WU VA57R-0375HU TV11R-055U UB10R-065U

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain

other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Mancy C. Brogdon
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Prescription Use (Per 21 CFR 801.109)  Ultrasound Device Indications Statement	Page 1 of 14
510(k) Number (if known):  Device Name: Diagnostic Ultrasound System SDU-1100, system	

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

						of Operat			Combined	Tissue	Other
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	(Specify)**	Harmonic Imaging	(Specify)
Ophthalmic				<u> </u>					<del> </del>	N	<u> </u>
Fetal		N	N	N		N	N	N	N	<del></del>	<del>                                      </del>
Abdominal		N	N	N		N	N	N	N_	N	
Intra-operative (Specify)											_
Intra-operative Neurological											_
Pediatric			<u> </u>		<u> </u>		<u> </u>			<del>                                     </del>	<u> </u>
Small Organ (Specify) *		N	N	N		N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic		<u> </u>		<u></u>		<u> </u>			<del>-  </del>	ļ <u> </u>	
Cardiac		N	N	N	<u> </u>	N	N	N	N N	N	-
Transesophageal		<u> </u>		<u> </u>		<u> </u>				<del>                                     </del>	ļ
Transrectal		N	N	N		N	N	N_	N	N	-
Transvaginal		N	N	N	1	N	N	N	<u> N</u>	N_	
Transurethral	<u> </u>		<u> </u>	<u> </u>	<u> </u>			ļ			<u> </u>
Intravascular		<u> </u>								<del></del>	
Peripheral Vascular		N	N	N	<u> </u>	N_	N	N	N	N	<del> </del>
Laparoscopic			<u> </u>		<u></u>			ļ <u>-</u>			<del>-</del>
Musculo-skeletal Conventional		N	N	N		N 	N	N	N	N	
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Other (Specify)								<u> </u>		1	<u> </u>

Other (Specify)							<u> </u>
N= new indication	n; P= previously	cleared by	FDA; E= add	ed under Ap	pendix E		
Other Indications	or Modes:					·	
* Thyroid, Testic	les, Breast				<u> </u>		
** B/M, B/PWD,		CFM(B)/C	CFM(M)				
		<u> </u>					
				<u></u>			
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		1	Division of Pa		_ <i>(</i> /		
		a	and Radiologic	Shoonclin	s, Abdomina	L ·	
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Prescription Use (Per 21 CFR 801.109) Ultrasound Device Indications Statement	Page 2 of 14
510(k) Number (if known):  Device Name: <u>Diagnostic Ultrasound System SDU-1100, L040-</u>	07 <u>5U</u>

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation Other Combined Tissue Color CWD Color Power PWDClinical Application A В M (Amplitude) (Specify)\*\* (Specify) Harmoni Velocity DopplerDoppler Imaging Imaging Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological Pediatric Small Organ N N Ν N N N N N (Specify) \* Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular N Ν N N N N N N Peripheral Vascular Laparoscopic N N N N N N Musculo-skeletal N N Conventional  $\overline{N}$ N N N N N Musculo-skeletal N N Superficial Other (Specify)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
* Thyroid, Testicles, Breast	
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM	M(M)
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	and Radiological Dovings
	610(k) Number K050510
	510(k) Number <u>K050510</u>

Prescription Use (Pe Ultra	r 21 sour	CFR 1d D	. 801 Pevi	.109) ce Ind	icatior	ıs Statem	ent Pag	e <u>3</u> of	14		
510(k) Number (if k Device Name : <u>Dia</u>	nowi gnosi	n) : _ tic U	ltrase	ound S	ystem S	DU-1100,	L040-120U				
Fill out one	for	n for	each	ultras	ound sy	stem or tra	nsducer.				
Indications for use:	Dia	gnos	tic u	ltrasou	nd imag	ing or Dop	pler analysis	of the hum	an body as fol	llows:	
					Mo	de of Opera	ation				<del></del>
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic					1						
Fetal	_										ļ
Abdominal	_								<u> </u>		
Intra-operative (Specify)											
Intra-operative			i '								
Neurological		<u> </u>			ļ				<del>- </del>		-
Pediatric		<u> </u>					ļ		<del>                                     </del>	_	<del>-</del>
Small Organ (Specify) *		N	N	N		N	N	N	N	N	<u> </u>
Neonatal											
Cephalic			<u></u>			<u> </u>				<del> </del>	<del> </del>
Adult Cephalic		1	<u> </u>		<u> </u>			<u></u>	_		<del></del>
Cardiac			<u> </u>						<del> </del>		<u> </u>
Transesophageal		<u> </u>				ļ <u> </u>		<u> </u>			<del> </del>
Transrectal	]										<del>-</del>
Transvaginal		]	<u> </u>		<u> </u>						<del> </del>
Transurethral				L						<u> </u>	_
Intravascular		T			<u>.                                    </u>			ļ	<u> </u>	<del> </del>	
Peripheral Vascular		N	N	N		N	N	N_	N	N	
Laparoscopic	1					<u> </u>		<u> </u>		<u> </u>	
Musculo-skeletal		N	N	N		N	N	N	N	N	
Conventional		1	<u> </u>					ļ			
Musculo-skeletal		N	N	N		N	N	N	N	N	
Superficial			<u> </u>		<u>.</u>	<u> </u>					
Others (Specify)		<u> </u>	<u> </u>	<u> </u>	<u></u>		<u></u>		<u> </u>	<u> </u>	
N= new indication;	P=	previ	ously	cleare	ed by FI	OA; E= add	ied under Ap	pendix E			
Other Indications of	r Mo	odes:					.,,				_
* Thyroid, Testicle											
** B/M, B/PWD, 0	FM	(B)/F	WD	, CFM	(B)/CFN	м(M)					<del>_</del>
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Prescription Use (Per 21 CFR 801.109) Ultrasound Device Indications Statement	Page 4 of 14
510(k) Number (if known):  Device Name: <u>Diagnostic Ultrasound System SDU-1100</u> , <u>L070-0</u>	<u>75U</u>

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation Other Tissue Combined Power Color CWD Color В М PWDClinical Application (Specify) Harmonic (Specify)\*\* (Amplitude) Velocity Doppler Imaging Doppler *Imaging* Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological Pediatric N Small Organ N N N N N N (Specify) \* Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular N N N N N Peripheral Vascular N N N Laparoscopic N N N N N N N N Musculo-skeletal Conventional N N N N N N N N Musculo-skeletal Superficial

Other Indications or Modes:

\* Thyroid, Testicles, Breast

\*\* B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Others (Specify)

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	and Radiological Devices KO50570

Prescription Use (Pe	er 21 sour	CFR nd D	801 Vevi	.109) ce Ind	ication	ıs Statem	ent Pag	e <u>5</u> of	<u>14</u> .		
510(k) Number (if k Device Name : <u>Dia</u>	now gnos	n) : _ tic U	ltrasc	ound Sy	stem S	DU-1100,	<u>L072-050U</u>				
Fill out one	e fon	m for	eact	ultraso	ound sy	stem or tra	nsducer.				
Indications for use:	Dia	onas	tic w	trasout	ad imag	ing of Dop	pler analysis	of the hum	an body as fol	llows:	
mulcations for use.	Dia	51100								•	
					Mo	de of Opera	ation			<del>  ==                                  </del>	101
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic						ļ	ļ			<u></u>	<del> </del>
Fetal	<u> </u>						<u> </u>	<b> </b>			<del> </del>
Abdominal						ļ <u>-</u>	<del> </del>	<u> </u>			<del> </del>
Intra-operative (Specify)											
Intra-operative		<b>1</b>									
Neurological					<u></u> .		<u> </u>				
Pediatric									<u> </u>		<del> </del>
Small Organ		N	N	N		N	N	N	N	N	
(Specify) *	↓	1	ļ.,					<u> </u>	<del>-</del>		<del> </del>
Neonatal		1			ļ		İ				
Cephalic	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<del> </del>	<u> </u>	<u> </u>	<del> </del> -		
Adult Cephalic	↓	<u> </u>			<u> </u>		<u> </u>			<u> </u>	
Cardiac	<u> </u>		<b> </b>	<u> </u>	<del>-</del>	-	<u>-</u>		<u> </u>		
Transesophageal	-	<b>├</b> -	├			<del> </del>		<del> </del>	<del> </del>		+
Transrectal	—	<del> </del>				<del></del>			-		1
Transvaginal	╁		-		<del> </del>	ļ. —	<del></del>	<del>                                      </del>		-	1
Transurethral	┼	<del>-</del>	├		<u> </u>	ļ	<del>-</del>			<u> </u>	<b>-</b>
Intravascular	-	   NT	NI	N	-	N	N	N	N	N	
Peripheral Vascular	╁	N	N	111	<del> </del>	18		<del>  - '`</del>	<del>- </del>		<u> </u>
Laparoscopic Musculo-skeletal	-	N	N	N		N	N	N	N	N	
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Conventional  Musculo-skeletal	+-	+	┼─		<del> </del>			-			
Superficial		1	1							<u> </u>	
Others (Specify)	1	<del> </del>	+-								<u> </u>
N= new indication;	P= :	nrevi	ously	v cleare	d by Fl	DA: E= ado	led under Ap	pendix E	<del></del>		
N- new indication,	, -	previ	ousi,	, 010410	0)	, —	•	-			
Other Indications of											
* Thyroid, Testicle							<del></del>				_
** B/M, B/PWD, 0	<u>CFM</u>	(B)/F	WD	, CFM(	B)/CFI	M(M)					
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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050510

Prescription Use (Per 21 CFR 801.109)  Ultrasound Device Indications Statement Page 6 of 14.											
510(k) Number (if k Device Name : <u>Diag</u>	nowi gnost	n) : _ tic <u>U</u>	ltr <u>as</u>	ound Sy	stem Sl	DU-1100, '	VA13R-035U	ī			
Fill out one	forr	n for	eacl	h ultraso	ound sy:	stem or trai	nsducer.				
Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:											
					Mod	le of Opera	tion				<u> </u>
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic				-							<u> </u>
Fetal		N	N	N		N	N	N	N	N_	ļ
Abdominal		N	N	N		N	N	N _	N	N	
Intra-operative								:		1	
(Specify)							ļ				
Intra-operative											
Neurological							ļ				ļ
Pediatric					<u></u>					ļ <u>.</u>	<del> </del>
Small Organ (Specify) *											
Neonatal		1			1						
Cephalic										ļ	
Adult Cephalic	1										<u> </u>
Cardiac		N	N	N		N	N	N	N	N	<u> </u>
Transesophageal											
Transrectal						<u> </u>					<del> </del>
Transvaginal							<u> </u>	<u> </u>			
Transurethral								<u> </u>			<del> </del>
Intravascular						<u> </u>					
Peripheral Vascular							<u> </u>				
Laparoscopic											<del> </del>
Musculo-skeletal											
Conventional		<u> </u>	<u> </u>	<u> </u>	<u> </u>			ļ	<u> </u>	<u> </u>	<del>                                     </del>
Musculo-skeletal											
Superficial		_	<u> </u>			<u> </u>	<del> </del>	<del> </del>		<del> </del>	<del> </del>
Others (Specify)				<u> </u>		<u> </u>	<u> </u>	<u> </u>		<u> </u>	
N= new indication;	P= 1	previ	ousl	y cleare	d by FI	A; E= add	led under App	pendix E			

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
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Concurrence of CDRH, Office of Device Evaluation (ODE)	

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices K050510

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Prescription Use (Pe	r 21 sour	CFR nd D	. 801 Jevi	.109) ce Ind	ication	is Statem	ent Page	e <u>7</u> of	14.				
510(k) Number (if k Device Name : <u>Dia</u>	nowi gnost	n) : _ iic U	ltrase	ound Sy	ystem S	DU-1100,	<u>VA13R-050U</u>	Ī					
Fill out one													
Indications for use:	Dia	gnos	tic u	ltrasoui	nd imag	ing or Dop	pler analysis	of the hum	an body as fol	llows:			
Mode of Operation  Mode of Operation  Color Combined Tissue Other													
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)		
Ophthalmic											<u> </u>		
Fetal		N	N	N_		N	N _	N	N	N_			
Abdominal		N	N	N	<u> </u>	N	N	N	N_	N_			
Intra-operative											İ		
(Specify)				<u> </u>						ļ			
Intra-operative													
Neurological					ļ. —		<del> </del>	<u> </u>	+		<del> </del>		
Pediatric	<u> </u>		<u> </u>	<u> </u>	<u> </u>	<del>                                     </del>			-		<del> </del>		
Small Organ					1			İ					
(Specify) *	ļ			-	<del> </del>	<del> </del>			<del> </del>		<del> </del>		
Neonatal							1						
Cephalic	ļ <u> </u>	<del>  -</del>		<del> </del>	<del> </del>	<del>                                     </del>	- <del> </del>	-					
Adult Cephalic	-	-	N	N	<u> </u>	N	N	N	N	N	<u> </u>		
Cardiac	-	N_	N	N	<del>                                     </del>	- 19	1	<del> '`</del>					
Transesophageal	<del> </del>	├	-	<del> </del>	┼	<del>                                     </del>		<del> </del>	<u> </u>				
Transrectal	┼	├	-	├	┼	-		1					
Transvaginal	-	<del> </del>	├	┼	<del> </del>	<del></del>			<del> </del>				
Transurethral	<del> </del>	-	-		<del> </del>	<del> </del>		<u> </u>			<del></del>		
Intravascular Peripheral Vascular	<del> </del>	-	-		<del> </del>	<del>  -</del>	-	1					
	┨──	<b>├</b> ─	├-	+-	<del> </del>	-		<del>                                     </del>					
Laparoscopic Musculo-skeletal	╅	-	-	-	┪┈┈		· · -	1					
Conventional		1						1					
Musculo-skeletal	╁	1	1			<u> </u>							
Superficial													
Others (Specify)	ļ	1	1	<b>-</b>					\		<u></u>		
N= new indication:	N= new indication; P= previously cleared by FDA; E= added under Appendix E												
Other Indications of	r Mo	des:		OF 10	D.V.CET	(0.0)	-			<del></del> -	_		
** B/M, B/PWD, 0	FM(	(B)/P	WD.	,CFM(	B)/CFM	I(M)					<del></del>		

Other Indications or Modes:

\*\*\* B/M, B/PWD, CFM(B)/PWD,CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)  Ultrasound Device Indications Statement Page 8 of 14.
510(k) Number (if known):  Device Name: <u>Diagnostic Ultrasound System SDU-1100</u> , VA20R-035U
Fill out one form for each ultrasound system or transducer.
Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of	f On	eration
141000		~: <del>~</del>

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic							ļ. <u> </u>		<del> </del>		
Fetal		N_	N	N_		N_	N	N	N	N_	
Abdominal		N	N	N		N	N	N	N _	N	<del> </del>
Intra-operative											1
(Specify)		<u> </u>									<u> </u>
Intra-operative			l	İ					1		
Neurological		<u> </u>	<u> </u>						<u> </u>	-	-
Pediatric		<u> </u>	<u> </u>						-		ļ
Small Organ											
(Specify) *		<u> </u>					<u></u>				<del> </del>
Neonatal		1									
Cephalic	ļ		<u> </u>					ļ. <del></del>	<del></del>		<del> </del>
Adult Cephalic	<u> </u>							<u> </u>	<del></del>	N	<del> </del>
Cardiac	<u> </u>	N	N	N	<u> </u>	N	N	N_	N	IN IN	- <del></del>
Transesophageal_	<u>L</u>		<u> </u>				<u> </u>	ļ <del></del> .	<u> </u>	<del> </del>	<del> </del>
Transrectal		<u> </u>		<u> </u>			<u> </u>	<u> </u>		<del> </del>	<del>  -</del>
Transvaginal	<u> </u>		1		ļ	ļ	<u> </u>	ļ			<del> </del>
Transurethral		<u> </u>		ļ		ļ <u></u>		<u> </u>			
Intravascular		1	<u> </u>		ļ <u>.</u>			<u> </u>	<u> </u>	<del> </del>	<del> </del>
Peripheral Vascular		<u> </u>								ļ	<del> </del>
Laparoscopic		<u> </u>			ļ	<u> </u>		<u> </u>	<del> </del>	<del>-</del>	<del> </del>
Musculo-skeletal							1				
Conventional							<b>_</b>	ļ —	<del></del>		<del> </del>
Musculo-skeletal								1			
Superficial	<u> </u>	<u> </u>	<u> </u>	<u> </u>	ļ			<del> </del> -		<del> </del> -	+
Others (Specify) N= new indication;	i		l		<u> </u>	<u> </u>	1	<u></u>		J	

Other Indications or Modes:

\*\* B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050510

Prescription Use (Pe	r 21 sout	CFR nd D	. 801 Jevi	.109) ce Ind	ication	is Statem	ent Pag	e <u>9</u> of	14			
510(k) Number (if known):  Device Name: <u>Diagnostic Ultrasound System SDU-1100, VA40R-035U</u>												
Fill out one form for each ultrasound system or transducer.												
Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:												
Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)	
Ophthalmic							<u> </u>				<u> </u>	
Fetal		N	N	N		N	N	N	N	N		
Abdominal		N	N	N		N	N	N	N	N	ļ	
Intra-operative (Specify)									ļ			
Intra-operative	-		-		† · ·							
Neurological					İ							
Pediatric Pediatric	<del>                                     </del>		1	<del> </del>	<u> </u>							
Small Organ	1	<u> </u>	_									
(Specify) *											<del> </del>	
Neonatal									1	ļ		
Cephalic		<u>.</u>		<u> </u>		<u> </u>	<del> </del>		<b>_ </b>		<u> </u>	
Adult Cephalic								ļ. <u></u>			<del> </del>	
Cardiac			<u> </u>	<u> </u>		<u> </u>		ļ				
Transesophageal		<u> </u>	_						<del>- </del>		<del> </del>	
Transrectal		<u> </u>	<u>L</u>	<u> </u>	1			ļ	<del>- </del>	<del> </del>		
Transvaginal			<u> </u>		<u> </u>			<del> </del>		<del> </del>	ļ. <u> </u>	
Transurethral	<u> </u>		<u> </u>	<u> </u>	_	-				<del> </del>	<u> </u>	
Intravascular	<u> </u>		<u> </u>	ļ					<del> </del>	<del></del>	<del> </del>	
Peripheral Vascular	<u> </u>		_	ļ			<u> </u>	<del> </del>	- <del> </del>		<del> </del>	
Laparoscopic		<u> </u>	<u> </u>	<b>_</b>			<u> </u>	<u> </u>	<del></del>	<del>                                     </del>	<del>                                     </del>	
Musculo-skeletal		1										
Conventional		<u> </u>	-	<b>↓</b>	<del></del>		<del>                                     </del>	<del> </del>		<del> </del>		
Musculo-skeletal			1				ł				1	
Superficial	ļ	1	4—	<del> </del>		<u> </u>		<del></del>		<del> </del>		
Others (Specify)	<u> </u>		<u></u>			<u> </u>	1 1 1 4	n andia 17		1		
N= new indication; P= previously cleared by FDA; E= added under Appendix E  Other Indications or Modes:												
D/IVI, D/F WD,	** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)											

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off) Division of Reproduction 

Prescription Use (Pe	er 21 soun	CFR d D	t 801 evic	.109) e Indi	cation	s Stateme	nt Page		f <u>14</u> .		
510(k) Number (if k Device Name : <u>Dia</u>	now gnos	n) : _ tic U	Itras	ound Sy	stem S	DU-1100, V	√ <u>A40R-035</u> E	<u>IU</u>			
Fill out one											
Indications for use:	Dia	gnos	stic u	ltrasour				of the huma	an body as fol	lows:	
<u></u>					Mod	le of Opera			<del></del>	I	Lou
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											<del> </del>
Fetal		N	N	N		N	N	N	N	N	<u> </u>
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative	1-							<b> </b>	ļ		
(Specify)	1	1	İ								<u> </u>
Intra-operative											
Neurological			l	1							ļ
Pediatric							ļ				<u> </u>
Small Organ		1									
(Specify) *					l						
Neonatal									-		
Cephalic							<u> </u>				ļ <u> </u>
Adult Cephalic									<u>.</u> .		
Cardiac	<u> </u>		1					<u> </u>			<u> </u>
Transesophageal	1										<u> </u>
Transrectal	1						l				
Transvaginal			1	<u> </u>	1					<u> </u>	
Transurethral	<del>                                     </del>	1	1		1		1				<u>                                     </u>
Intravascular	1	1									
Peripheral Vascular	1		1	· <del></del>	T-						<u> </u>
Laparoscopic	$t^-$	i	$t^-$		1						
Musculo-skeletal	-	$t^-$	1		<del> </del>	<u> </u>					
Conventional		1		1							
Musculo-skeletal	1-	<u> </u>		<u> </u>	1						
Superficial								j			
Others (Specify)	$\dagger$	†	1	<u> </u>	1						
N= new indication;	P= 1	previ	ousl	y cleare	d by FI	A; E= add	ed under App	endix E			
Other Indications of				CFM(I	B)/CFM	I(M)			<del>.</del>		_
Bilti, Bil (12)		<u></u>		, , , ,		<u> </u>					<del></del>
	_		_	-							
	PLEA	SE DO	TON	WRITE B	ELOW TH	IS LINE-CONT	INUE ON ANOT	HER PAGE IF I	NEEDED)		_
				Concurrer	nce of CDF		vice Evaluation (C		^		
		V				(Divis	) a sion Sign-O	ncy C	Brogdo	n	<del></del>
									Abdominal,		
						F 49	o wamber .		E W	J · · ·	<del></del>

Prescription Use (Pe	er 21 soun	CFR d D	R 801 evic	.109) e Indi	cation	s Stateme	ent Page	: <u>11</u> o	f_ <u>14</u>			
510(k) Number (if known):  Device Name: Diagnostic Ultrasound System SDU-1100, VA57R-0375WU												
Fill out one form for each ultrasound system or transducer.												
Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:  Mode of Operation												
				<u> </u>			<del> </del>	·	16.11	T:	Other	
Clinical Application	À	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	(Specify)	
Ophthalmic			<u> </u>									
Fetal	_	N	N	N		N	N	N	N	N		
Abdominal		N	N	N		N	N	N	N	N	<u> </u>	
Intra-operative (Specify)												
Intra-operative	1		<u> </u>								1	
Neurological											ļ	
Pediatric		<u> </u>									<u> </u>	
Small Organ					1				ĺ			
(Specify) *	1				l	<u> </u>					ļ.—	
Neonatal												
Cephalic		<u> </u>	<u> </u>	ļ	<u> </u>	<u> </u>		ļ <del></del>	<del>-</del>		<del> </del>	
Adult Cephalic	<u> </u>		ļ			<del> </del>			<u> </u>	<u> </u>	<del> </del>	
Cardiac	<u> </u>	<u> </u>	↓	ļ	<u> </u>	<u> </u>	-l		- <del></del>	<u> </u>	ļ	
Transesophageal		_	<u> </u>	ļ	<u> </u>	<u> </u>		<u> </u>			<del> </del>	
Transrectal	<b> </b>	<u> </u>	<u> </u>			<del> </del>		ļ <u> </u>				
Transvaginal	<u> </u>		ļ	ļ	<del> </del>			<del> </del>	<del>- </del>		<del> </del>	
Transurethral	1_	<u> </u>	<u> </u>	ļ <u>.</u>		ļ	_	<del> </del>				
Intravascular		<u> </u>				<u> </u>	-	ļ	<del>- </del>		-	
Peripheral Vascular	ļ	ļ				<del> </del>	<u> </u>	<del></del>	<del></del>			
Laparoscopic	<u> </u>	<u> </u>	_		4	<del> </del>			<del> </del>	-	<del>                                     </del>	
Musculo-skeletal												
Conventional	<u> </u>	<u> </u>	ļ		<b>}</b> -					<del> </del>	<del>                                     </del>	
Musculo-skeletal					1						1	
Superficial	<del> </del>	<b>↓</b> —	-	<del>  -</del> -	<u> </u>	<del> </del>		<del> </del>	<del>-</del>	<u> </u>		
Others (Specify)	N= new indication; P= previously cleared by FDA; E= added under Appendix E											
				y cleare	d by FI	)A; E= add	ied under Ap <sub>l</sub>	pendix E	•			
	Other Indications or Modes:  ** B/M, B/PWD, CFM(B)/PWD,CFM(M)											
D/M, D/I WD, C	>T 1AT	1.7.1		, 0 - 1 - 1 (	- ,	<u> </u>						

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal. and Redictogral Devices 5 FOR) Number \_\_\_\_\_

Prescription Use (Pe Ultras	r 21 oun	CFR d D	evic	.109) e Indi	cation	s Stateme	ent Page	<u>12</u> o	f <u>14</u> .		
510(k) Number (if k Device Name : <u>Dia</u>	now gnos	n) : _ tic U	ltras	ound Sy	stem S	DU-1100,	VA57R-0375	<u>HU</u>			
Fill out one	for	n for	eacl	n ultras	ound sy	stem or tra	nsducer.				
Indications for use:	Dia	gnos	stic u	ltrasour	nd imag	ing or Dop	pler analysis	of the hum	an body as fol	llows:	
					Mod	de of Opera	ation				
Clinical Application	Á	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic					-						1
Fetal		N	N	N		N	N	N	N	N	<u> </u>
Abdominal		N	N	N		N	N	N	N	N	<u> </u>
Intra-operative		<u> </u>	-			-					
(Specify)						1					
Intra-operative											
Neurological									<u> </u>		<u> </u>
Pediatric											<u> </u>
Small Organ											1
(Specify) *	ŀ										<u> </u>
Neonatal									1		
Cephalic											ļ
Adult Cephalic						<u></u>	<u> </u>	ļ			<u> </u>
Cardiac								<u> </u>			ļ
Transesophageal						<u></u>					
Transrectal											
Transvaginal	1			i							<u> </u>
Transurethral										ļ <u> </u>	
Intravascular											
Peripheral Vascular				T							
Laparoscopic											
Musculo-skeletal	Ì					]					
Conventional										ļ	<del> </del>
Musculo-skeletal	1							1			
Superficial			<u>L</u> _	<u> </u>							<del> </del>
Others (Specify)	1	1					Ī				

Other Indications or Modes:

\*\* B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (P	er 21 oun	CFF d D	R 80 evic	1.109) e Indi	cations	s Stateme	ent Page	13_of	f <u>14</u> .				
510(k) Number (if k Device Name : <u>Dia</u>	nowi gnost	n) : _ tic U	itras	ound Sy	stem S	DU-1100,	TV11R-055U	<u>I</u>					
Fill out one	fort	n for	eacl	h ultrasc	ound sy	stem or trai	nsducer.						
Indications for use:	Dia	gnos	tic u	ltrasoui	nd imag	ing or Dop	pler analysis	of the huma	an body as fol	lows:			
Mode of Operation													
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)		
Ophthalmic							<u> </u>						
Fetal		N	N	N		N	N	N	N N	N			
Abdominal							ļ <u>.</u>		<u> </u>				
Intra-operative						ļ							
(Specify)											<del> </del>		
Intra-operative			İ				1	]	1				
Neurological	<u> </u>	_		<u> </u>			<u> </u>		<del></del>		<u> </u>		
Pediatric	<u>L</u>	<u> </u>		<u> </u>				<u> </u>	<del> </del>	<u> </u>	<del>                                     </del>		
Small Organ			İ										
(Specify) *	<u> </u>		<u>L</u>	<u> </u>							<del> </del>		
Neonatal		1		1									
Cephalic		<u> </u>		<u> </u>			<del>-</del>	<del> </del>	<u> </u>		<del> </del>		
Adult Cephalic		<u> </u>	$oldsymbol{ol}}}}}}}}}}}}}}}}}}$			ļ			<del></del>		<del> </del>		
Cardiac	<u>L</u> .	<u> </u>	<u> </u>	ļ				-	<del></del> -		-		
Transesophageal	<u> </u>			<u> </u>	<u> </u>		ļ., <u> </u>	ļ	- NT	N	<del>.  </del>		
Transrectal		N	N	N	ļ	N	N	N N	N	N	<del> </del>		
Transvaginal	1	N	N	N	ļ	N	N	N	N	IN_	<del> </del>		
Transurethral		<u> </u>	<u> </u>	ļ	ļ		<del>-</del>		<del></del>				
Intravascular	<u> </u>		<u> </u>					<u> </u>	<del> </del>	<del> </del>	-		
Peripheral Vascular		<u> </u>	<u> </u>	<u> </u>			ļ	<u> </u>			<del></del>		
Laparoscopic	<u> </u>		1	<u> </u>		<u> </u>	<u> </u>	<u> </u>		<del> </del>	<del> </del>		
Musculo-skeletal													
Conventional	<u> </u>	<u> </u>	<u> </u>			<del> </del>		ļ		<del> </del>			
Musculo-skeletal			1						1				
Superficial	<u> </u>	1	1_	ļ				<del> </del>	+	<del>                                       </del>	<del> </del>		
Others (Specify)	<u>L_</u>	<u>L.,</u>	<u>L</u>	<u></u>	<u> </u>	<u>L</u>	<u> </u>	<u> </u>	<u> </u>				
	N= new indication; P= previously cleared by FDA; E= added under Appendix E												
Other Indications of	11/1	Jucs.											

Other Indications or Modes:

\*\*\* B/M, B/PWD, CFM(B)/PWD,CFM(M)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Park angular Devices 2050:

Prescription Use (Pe Ultras	r 21 oun	CFR d D	. 801 evic	.109) e Indi	cation	s Stateme	ent Page	e <u>14</u> o	f <u>14</u> .				
510(k) Number (if k Device Name : <u>Dia</u>	now	n) : _ tic U	ltras	ound Sy	ystem S	DU-1100,	<u>UB10R-065U</u>	<u>ī</u>					
Fill out one													
Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:  Mode of Operation													
	,				Mod	le of Opera	ation						
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)		
Ophthalmic									<b></b>		<u> </u>		
Fetal											<del> </del>		
Abdominal							<u> </u>				<u> </u>		
Intra-operative (Specify)													
Intra-operative Neurological													
Pediatric				<u> </u>			ļ		<u> </u>		ļ		
Small Organ (Specify) *													
Neonatal		-											
Cephalic			l		1		ļ						
Adult Cephalic	<del>                                     </del>	1	<del> </del>	<u>├</u>	<del></del>								
Cardiac	-		-										
Transesophageal	├-		<del>                                     </del>	<del>                                     </del>									
Transrectal	<del> </del>	N	N	N		N	N	N	N	N			
Transvaginal	$\vdash$	<del> </del>	<del>                                     </del>										
Transurethral	1	-		<del>                                     </del>	<b>†</b>	ļ. <del></del>							
Intravascular	$\vdash$	1—	<del>                                     </del>		<b>-</b>	-			T				
Peripheral Vascular	<del> </del>	<del>                                     </del>	$\vdash$	<del> </del>	1								
Laparoscopic	<del> </del>	十一	$\vdash$	<del> </del>	1 -	<del></del>							
Musculo-skeletal		+-	<del>                                     </del>										
Conventional										1			
Musculo-skeletal	_	<del>                                     </del>		1	<u> </u>	<del></del>							
Superficial		1											
Others (Specify)		1	1							<u> </u>			
N= new indication;	P= 1	previ	ousl	y cleare	d by FL	A; E= add	led under Ap	pendix E					
Other Indications o											_		
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)													
	DI E A	SE DO	NOT	WRITE B	ELOW TH	IS LINE-CON	TINUE ON ANOT	HER PAGE IF !	NEEDED)		_		
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(Division Sign-Off)

Of Reproductive, Abdominal,

Addictological Devices

10(k) Number

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